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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,402	07/30/2003	Patrice Flaherty	1066	9003
7590 03/24/2006				
R. Keith Harrison 2139 E. Bert Kouns Shreveport, LA 71105		EXAMINER HOEKSTRA, JEFFREY GERBEN		
		ART UNIT 3736		PAPER NUMBER
DATE MAILED: 03/24/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/630,402	FLAHERTY, PATRICE	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 12-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 24-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Prager (4257416). Prager discloses a multi-channel device for collecting and administering medical fluid to a patient, comprising: a main tubing segment 16 for the passage of blood and medical fluids, an indicator unit 45 and a syringe port(s) 40,44 disposed in fluid communication with said main tubing segment in a branched relationship with each other, where said indicator unit is adapted for indicating blood content and having a constant volume by using a bottle inherently capable of not only drug administering but fluid collection (column 2 lines 36-40), and a clamp 52 operably engaging main tubing segment for selectively blocking fluid.
3. For claims 2 and 4, Prager shows a syringe or blood volumeter (column 4 line 5) provided in said indicator unit.
4. For claims 3 and 6, Prager discloses an indicator unit disposed in removable fluid communication with said main tubing unit in Figure 1.
5. For claim 5, Prager shows a volumeter chamber 45 or a graduated syringe.
6. For claim 32, Prager discloses a port(s) 40,44 in fluid communication with said indicator unit, an attachment sleeve(s) 34,36,38 in fluid communication with said port,

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and a blood receptacle (column 1 lines 37-41 and column 2 lines 36-40) in fluid communication with said sleeve.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prager in view of Wilkinson et al (6235010). Prager discloses the claimed combination drug administration- blood withdrawal apparatus except for the air permeable membrane. Wilkinson et al teaches an air permeable membrane 64 disposed to prevent the escape of the specimen within the collector while allowing air to pass (column 3 line 59) wherein a constant volume specimen receptacle 82, a test tube or bottle, is adapted to receive said specimen via gravity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination blood collection- fluid administration device as taught by Prager, with Wilkinson since it was known in the art that Wilkinson is used to provide a means for maintaining atmospheric pressure within the device such that no pressure differential exists to hinder fluid transport and in addition to prevent escape or leakage of specimen.

9. For claims 8 and 10, Prager shows a graduated syringe or blood volumeter chamber (column 2 lines 36-40 and column 4 line 5) provided in said indicator unit.

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10. For claims 9 and 11, Prager discloses an indicator unit disposed in removable fluid communication with said main tubing unit in Figure 1.

11. Claims 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prager in view of Wilkinson et al. Prager discloses the claimed combination drug administration- blood withdrawal apparatus, except for the membrane conduit and air permeable membrane, comprising a main tubing segment 16, an indicator unit 45 and a port(s) 40,44 disposed in fluid communication with said main tubing segment in a branched relationship with each other, where said indicator unit is adapted for indicating blood content and having a constant volume by using a bottle inherently capable of not only drug administering but fluid collection (column 2 lines 36-40), and a clamp 52 operably engaging main tubing segment for selectively blocking fluid. Wilkinson et al teaches an air permeable membrane 64 in fluid communication with a membrane conduit 40 disposed to prevent the escape of the specimen within the collector while allowing air to pass (column 3 line 59) wherein a constant volume specimen receptacle 82, a test tube or bottle, is adapted to receive said specimen via gravity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination blood collection- fluid administration device as taught by Prager, with Wilkinson since it was known in the art that Wilkinson is used to provide a means for maintaining atmospheric pressure within the device such that no pressure differential exists to hinder fluid transport and in addition to prevent escape or leakage of specimen.

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12. For claim 25, Prager discloses connectors in fluid communication with said main tubing segment and in removable fluid communication with said indicator unit (column 1 lines 37-41).

13. For claim 26, Prager shows a graduated syringe or blood volumeter chamber (column 2 lines 36-40 and column 4 line 5) provided in said indicator unit.

14. For claims 27-29, Prager discloses a collection conduit with (column 2 lines 36-40), a graduated intravenous bag or bottle with constant volume disposed in a branched relationship with said indicator unit wherein port(s) 40,44 is/are disposed therebetween, in fluid communication with said main tubing segment and said indicator unit.

15. For claim 30, Prager discloses a tubing segment(s) 28,30,32 in fluid communication with said main tubing segment with a port disposed thereon.

16. For claim 31, Prager discloses a connector 20,18a disposed on said main tubing segment between said clamp region and indicator-port region as best seen in Figures 1 and 2.

Response to Arguments

17. Applicant's arguments filed 11/29/2005 have been fully considered but they are not persuasive. For claims 1-6, Applicant argues the indicator unit, a syringe, of Prager has a variable volume; however, Prager discloses the use of constant volume bags and bottles for administration of therapeutics that are inherently capable of being disposed as receptacles.

18. For claims 7-11 and in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can

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only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Prager and Wilkinson et al both disclose specimen collection means removably coupled to specimen collection systems containing a means for altering the internal pressure of the apparatus, the vents in Prager and the air-permeable membrane in Wilkinson et al. Applicant argues Prager teaches the withdrawal of blood via the vacuum pressure created by a syringe and that the syringe performs the function of Wilkinson et al's air-permeable membrane if incorporated; however, Prager discloses the use of constant volume bags and bottles that are filled/emptied via gravity induced pressure differentials wherein said pressure differentials can be altered via vent holes that are functionally similar in effect to that of Wilkinson et al's air-permeable membrane.

Conclusion

19. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH

JGH

Max F. Hindenburg

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SUPERVISOR
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